

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AZURITY PHARMACEUTICALS, INC.,

Plaintiff,

v.

**EDGE PHARMA, LLC f/k/a,
EDGE PHARMACY SERVICES, LLC,**

Defendant.

Civil Action No. 1:20-cv-10280-RWZ

**MEMORANDUM IN SUPPORT OF PLAINTIFF’S MOTION
FOR JUDGMENT**

Before Defendant Edge Pharma, LLC f/k/a Edge Pharmacy Services, LLC (“Edge” or “Defendant”) ceased doing business in 2022 — after the FDA required Edge to conduct a nationwide, voluntary recall of all of its products — Edge was mass producing vancomycin hydrochloride for oral solution in violation of FDA regulations and in a manner that threatens the safety and effectiveness of the drug and puts at risk the health of the public. Even worse, Edge falsely advertised that it was complying with all regulations applicable to an “outsourcing facility” to induce hospitals, surgery centers, clinics, and other health care providers to buy its vancomycin, rather than safe, effective, and FDA-approved vancomycin produced by Plaintiff Azurity Pharmaceuticals, Inc. (“Azurity”) f/k/a CutisPharma, Inc.

Azurity sued Edge alleging that its false and deceptive advertising violated section 43(a) of the Lanham Act and constituted an unfair and deceptive trade practice in violation of Chapter 93A of the Massachusetts General Laws (“Chapter 93A”). Azurity alleged that Edge was violating several provisions of Section 503B of the Food, Drug, and Cosmetics Act (“FDCA”), which sets forth requirements for an outsourcing facility like Edge. Edge filed a motion to dismiss, which was granted. On appeal, however, the First Circuit determined that Azurity had successfully alleged a

Lanham Act and Chapter 93A claim against Edge, based on Edge's statements that it complied with section 503B while it used an unauthorized "bulk drug substance" to compound its product, thereby violating section 503B(a)(2)(A). Based on this conclusion, the First Circuit remanded the case for further proceedings on this theory of liability.

While the appeal was pending, FDA regulators found Edge in violation of the FDCA and requested that Edge issue a voluntary, nationwide recall of all its products. Subsequently, the FDA filed a complaint in federal court seeking to permanently enjoin Edge from violating the FDCA. On June 10, 2022, the court entered a consent decree prohibiting Edge from manufacturing, holding, or distributing any product until it demonstrated compliance with the FDCA. By the time the consent decree was entered, however, Edge's founder and CEO, William Chatoff, announced the closing of the company.

The First Circuit issued its opinion on August 8, 2022. Upon remand to this Court, Edge's counsel in this case filed motions to withdraw their appearance on the grounds that Edge was defunct and had failed to pay its legal fees. The Court set a status conference for January 12, 2023, requiring all parties and counsel to appear in person. The hearing was held, and Edge failed to appear in violation of the Court's Order.

Azurity therefore submits the instant motion for judgment pursuant to the Court's instructions during the January 12, 2023 Status Conference. Edge has already conceded that it violated the Lanham Act and Chapter 93A. Indeed, Edge admitted in an affidavit previously submitted to this Court that it used a bulk drug substance to manufacture its vancomycin product in a manner that violated section 503B. As a result, its compliance representations were literally false. Accordingly, Azurity is entitled to judgment in its favor and disgorgement of Edge's profits,

estimated at \$ [REDACTED]. The basis for Azurity's damages is set forth below and in the affidavit attached as Exhibit F.

FACTUAL BACKGROUND

I. Azurity Produces FDA-Approved FIRVANQ®.

Azurity is a specialty pharmaceutical company that specializes in providing safe, high-quality treatment for patients requiring customized formulations for their care. Mem. In Supp. of Pls. Mot. for Prelim. Inj., Ex. A, Decl. of S. Monahan ¶ 2 (ECF No. 3-1) (attached hereto for convenience as Exhibit A). One such product is FIRVANQ®. FIRVANQ® is an FDA-approved vancomycin hydrochloride for oral solution indicated for treatment of *Clostridium difficile*-associated diarrhea and Enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains. *Id.* ¶¶ 5–6.

While seeking FDA approval of FIRVANQ®, Azurity invested significant time and resources to research, develop, and test FIRVANQ® to ensure its safety and effectiveness. *Id.* ¶ 11. It took approximately four years for Azurity to obtain FDA approval of FIRVANQ®. *Id.* ¶ 14. On January 26, 2018, the FDA approved New Drug Application Number 208910 for FIRVANQ®. *Id.* ¶ 13. FIRVANQ® was the only FDA-approved vancomycin hydrochloride for oral solution between April 2, 2018 and September 11, 2019. *Id.* ¶ 7. Since September 11, 2019, FIRVANQ® has been one of two FDA-approved vancomycin hydrochlorides for oral solution. *Id.* ¶ 6. (The other approved drug is not the Edge product.) FDA approval of FIRVANQ® means that consumers and medical professionals can rely upon its safety and efficacy. FIRVANQ® is one of Azurity's most successful products and constitutes a substantial portion of Azurity's revenue. *Id.* ¶¶ 15–16.

II. Edge Mass-Manufactured Vancomycin Using a Bulk Drug Substance.

At all times relevant to the Complaint (which was filed on February 12, 2020), Edge claimed to be a compounding facility that produced sterile and non-sterile compounded

medications for hospitals, surgery centers, and clinics. *See* Compl. ¶ 27; Declaration of William Chatoff, ¶¶ 6, 9, 12, (Mar. 27, 2020), ECF 25 (attached hereto for convenience as Exhibit B) (“Chatoff Decl.”). Beginning in February 2018, Edge produced and marketed an oral vancomycin solution that competed directly with Azurity’s FIRVANQ®. *See* Compl. ¶ 32; Ex. B, Chatoff Decl. ¶ 14. Indeed, Azurity and Edge targeted the same customers: individual patients and health care providers including surgery centers, hospitals, and clinics. *See* Compl. ¶ 19; Ex. B, Chatoff Decl. ¶ 12.

In the Declaration of William Chatoff, Edge’s CEO admitted that “Edge is no longer using a non-FDA-approved ‘bulk drug substance’ to compound its vancomycin oral solution product. The last production date of Edge’s product that was made with a bulk chemical was February 20, 2020.” Ex. B, Chatoff Decl. ¶ 20. Edge therefore admitted that it was using a bulk drug substance prior to February 20, 2020 to manufacture its vancomycin product. As discussed below, Edge’s use of a bulk drug substance violated section 503B of the FDCA.

III. Edge Engaged in False and Deceptive Advertising and Promotion.

Edge’s website was littered with misrepresentations about its compliance with FDA regulations, particularly due to its non-compliant and likely unsafe production of vancomycin. The following statements (the “Compliance Statements”) were published on Edge’s website:

- “Edge Pharma is a pharmaceutical sterile and non-sterile 503B Outsourcing Facility offering high quality, innovative solutions for the health care community.” EDGEpharma, Home Page, <https://edgepharma.com/> (last visited February 11, 2020) (“EDGEpharma”).
- “As your compliance partner, we are dedicated to providing turnkey 503B outsourcing with the highest level of quality, easy ordering, simple logistics, and excellent customer support.” *Id.*
- “Our facility is compliant with the following state, local, and federal regulations and guidelines:

USP 795, USP 797, USP 800

Occupational Safety and Health Administration (OSHA)
Food and Drug Administration (FDA)
US Pharmacopeia (USP)
Applicable Good Manufacturing Practice (GMP) Guidelines.”

EDGEpharma, About Us, <https://edgepharma.com/about-us/> (last visited February 11, 2020).

Compl. ¶ 61; *see also* Exhibit C.

The Compliance Statements were deceptive because they expressly stated that Edge complied with FDA regulations and, as a result, was producing drugs that are legal, safe, and effective. *Id.* ¶¶ 63-64. The Compliance Statements were made to health care providers for the purpose of having them rely on them in deciding to purchase Edge’s vancomycin (and other products). *Id.* ¶ 65. As discussed further below, these statements constitute violations of the Lanham Act and Chapter 93A.

IV. Edge Has Ceased All Operations and Is No Longer Participating in This Lawsuit.

In November 2021, the FDA conducted an inspection of Edge and found numerous concerns and issues as identified in a Form 483 inspection report. After the inspection, and because the inspection found violations of the FDCA and issues so serious that patient safety was a concern, the FDA requested Edge voluntarily recall all drugs within expiry and cease production and distribution of all products. *See* Compl. ¶ 63, *United States vs. Edge Pharma* (D. Vt. May 20, 2022), ECF 1 (attached hereto as Exhibit D). Edge issued the voluntary, nationwide recall on December 4, 2021. Subsequently, however, Edge “disputed the significance of the insanitary conditions and CGMP deficiencies . . . including the mold recoveries, bacterial recoveries, inadequate airflow patterns, inadequate air pressure differentials, the presence of pests, product sterility and endotoxin failures, and inadequate investigations by the Quality Unit.” *Id.* In addition, Edge informed FDA that it intended to resume operations in late February or early March 2022. *Id.* After further discussions with FDA, Edge agreed to wait for FDA concurrence before re-

opening. But given Edge’s “history of failing to heed FDA’s warnings to resolve deficiencies, particularly [Edge’s] failure to establish and follow procedures to prevent microbial contamination of sterile drug products,” FDA believed that Edge would continue to violate regulations unless permanently enjoined by a Court. *Id.* ¶ 65. As such, FDA filed the Complaint against Edge seeking a permanent injunction.

On June 10, 2022, the Court entered a consent decree permanently enjoining Edge from manufacturing, holding, or distributing any product until it was deemed in compliance with applicable regulations. *See generally* Consent Decree, *United States vs. Edge Pharma* (D. Vt. May 20, 2022), ECF 1 (attached hereto as Exhibit E). But even before then, on May 31, 2022, Edge announced it was shutting down all operations. As of today, Edge remains closed, but it has not filed bankruptcy or other insolvency proceedings as far as Azurity has been able to determine.

On December 13, 2022, after the First Circuit remanded this case for further proceedings, William Egan, Esq. and Julianna Carpenter, Esq. moved to withdraw their representation of Edge, stating that (a) they had been unable to communicate with their client despite repeated attempts, (b) Edge was no longer operating, and (c) Edge had failed to pay its legal fees. *See* ECF 56. On December 29, 2022, Robert Fluskey, Esq. likewise moved to withdraw his representation of Edge for the same reasons. *See* ECF 58. The Court entered an order scheduling a status conference for January 12, 2023, ordering all parties and counsel to appear in person. *See* ECF 57. The status conference was held on January 12, 2023, and Edge did not appear. The Court granted counsels’ motions to withdraw, and Edge currently is unrepresented.

ARGUMENT

Azurity seeks relief for Edge’s unfair competition and false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a) and its unfair and deceptive trade practices in violation of Massachusetts General Laws Chapter 93A. Edge failed to comply with the requirements of Section

503B(a)(2)(A), rendering its statements that it complied with all applicable laws and regulations literally false and misleading.¹ As such, Azurity is entitled judgment in its favor as well as statutory damages.

I. Edge Violated the Lanham Act and Chapter 93A By Making False Representations About Its Compliance with the FDCA.

A. Edge Admitted its Failure to Comply with the Bulk Drug Requirements of Section 503B.

Edge claimed to be exempted from FDA pre-approval requirements based on its registration as an “outsourcing facility” pursuant to section 503B of the FDCA. Compl. ¶¶ 31, 61. Outsourcing facilities are permitted to sell quantities of compounded drugs directly to hospitals and health care professionals without obtaining individual patient prescriptions, and without pre-market approval from the FDA, provided the facility satisfies certain requirements set forth in Section 503B, 21 U.S.C. § 353b. *Id.* ¶ 21.

Edge admitted that prior to February 20, 2020, it used a “bulk drug substance” to produce its vancomycin. Pursuant to section 503B, an outsourcing facility may only compound with a “bulk drug substance” if that substance appears on an FDA list “identifying bulk drug substances for which there is a clinical need,” 21 U.S.C. § 353b(a)(2)(A)(i), or if “the drug compounded from such bulk drug substance appears on the drug shortage list.” *Id.* § 353b(a)(2)(A)(ii). Compl. ¶ 22. The active ingredient in FIRVANQ® and in Edge’s vancomycin is vancomycin hydrochloride. *Id.* ¶ 40; Ex. A, Decl. of S. Monahan ¶ 10. The FDA has not yet issued a final 503B Bulk Drug List but has a list of bulk drug substances nominated for placement on the 503B Bulk Drug List (the “503B Nominated Bulk Drug List”). Vancomycin hydrochloride appears on the 503B Nominated

¹ On appeal, the First Circuit remanded Azurity’s claim that Edge’s Compliance Statements expressly stating its compliance with applicable laws and regulations were false because Edge had violated Section 503B(a)(2)(A).

Bulk Drug List as a “Category 1” drug. Compl. ¶ 50. Nevertheless, pursuant to the FDA’s interim policy with respect to the 503B Bulk Drug List, the FDA treats Category 1 drugs as if they do not appear on the 503B Bulk Drug List. *Id.* ¶¶ 49-51. In short, there was no clinical need for vancomycin hydrochloride identified by the FDA that would justify Edge’s use of a bulk drug substance. In addition, FIRVANQ® is not listed on the drug shortage list. *Id.* ¶ 42. As a result, Edge did not satisfy either of the exceptions which would permit it to use a bulk drug substance to compound its vancomycin product.

Thus, prior to February 20, 2020, and by its own admission, Edge failed to comply with this requirement of section 503B. Accordingly, at least until the Complaint in this case was filed, Edge’s production of vancomycin was not compliant with FDA regulations.

B. As a Result, Edge Made False Representations in Violation of the Lanham Act (Count I) and Chapter 93A (Count II).

Edge repeatedly stated on its website that it complied with all applicable laws and regulations, including the FDCA. Considering Edge’s violation of section 503B’s bulk drug provision, these Compliance Statements were literally false.

To establish a claim pursuant to the section 43(a) of the Lanham Act, Azurity must, and has, established the following:

- (1) Defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about its own or another’s product;
- (2) the misrepresentation is material, in that it is likely to influence the purchasing decision;
- (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;
- (4) Defendant placed the false or misleading statement in interstate commerce; and
- (5) Plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310–11 (1st Cir. 2002). Azurity can successfully prove each of these elements.

1. Edge’s Website Contained False and Misleading Statements.

Literally false statements constitute a violation of the Lanham Act. *Cashmere*, 284 F.3d at 311. Edge made three literally false Compliance Statements on its website², expressly stating that it complied with applicable laws and regulations, including regulations issued by the FDA. Compl. ¶ 61; *see also* Ex. C. However, Edge used a bulk drug substance to produce its vancomycin product, thereby violating the bulk drug substance requirements in 21 U.S.C. § 353b(a)(2)(A). Thus, contrary to its representations, Edge was not compliant with applicable FDA regulations and guidelines, and the compliance statements on its website were literally false.

2. Edge’s False and Misleading Statements were Deceptive.

The First Circuit applies a presumption of consumer deception to all literally false statements. *See Cashmere*, 284 F.3d at 314 (affirming that the First Circuit applies a presumption of consumer deception to all literal falsity claims); *Riverdale Mills Corp. v. Cavatorta N. Am., Inc.*, 146 F. Supp. 3d 356, 362 (D. Mass. 2015). “If the advertisement is literally false, the court may grant relief without considering evidence of consumer reaction.” *Clorox Co. Puerto Rico v. Proctor & Gamble Com. Co.*, 228 F.3d 24, 33 (1st Cir. 2000). Edge’s statements were literally false, and thus Azurity is not required to establish actual customer deception.

3. Edge’s Deception was Material.

Edge’s deception was undoubtedly material. “The materiality component of a false advertising claim requires a plaintiff to prove that the defendant’s deception is ‘likely to influence the purchasing decision.’” *Cashmere*, 284 F.3d at 311 (quoting *Clorox*, 228 F.3d at 33 n. 6). “One

² All the statements at issue in Azurity’s Complaint appeared on Edge’s website and were made in a “commercial” context.

method of establishing materiality involves showing that the false or misleading statement relates to an ‘inherent quality or characteristic’ of the product.” *Id.* at 311–12 (citation omitted).

Safety and effectiveness are of the highest concern when health care providers and patients purchase pharmaceuticals — particularly in a hospital setting. Indeed, the purpose of section 503B requirements is to mitigate the risk to public health. Health care providers and consumers relied on Edge’s representations that it is compliant with section 503B and other applicable FDA regulations when making purchasing decisions. Health care providers and consumers would likely have chosen not to purchase vancomycin from Edge if they knew that Edge was not complying with section 503B’s requirements and was instead producing an unsafe product. Thus, Edge’s misrepresentations are material, “because it relates to a characteristic that defines the product at issue, as well as the market in which it is sold.” *Id.* at 312.

4. Edge’s Statements Entered Interstate Commerce.

Edge’s misrepresentations appeared on the company’s website. The website was viewable throughout the United States and the world, and thus the statements and the products entered interstate commerce. *See McGrath & Co. v. PCM Consulting, Inc.*, No. Civ. .A. No. 11-10930, 2012 WL 503629, at *6 (D. Mass. Feb. 15, 2012) (“[W]hen one operates a website containing alleged false or misleading statements, the party causes those statements to enter interstate commerce through the internet.”).

5. Edge’s Misrepresentations Constitute Unfair and Deceptive Acts under Chapter 93A (Count II).

Chapter 93A prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Mass. Gen. Laws ch. 93A, § 2(a). Business practices are generally considered “unfair” pursuant to Chapter 93A if they are “immoral, unethical, oppressive, or unscrupulous” or fall “within the penumbra of a common law, statutory,

or other established concept of unfairness.” *Morrison v. Toys “R” Us, Inc.*, 806 N.E.2d 388, 392 (Mass. 2004) (quoting *Heller Fin. v. Ins. Co. of N. Am.*, 573 N.E.2d 8, 12–13 (Mass. 1991)). “Misleading or false advertising is actionable under Chapter 93A by a competitor damaged by such advertising.” *McGrath & Co.*, 2012 WL 503629, at *8. Edge’s false statements thus constitute a violation of Massachusetts’ unfair trade practices laws.

Accordingly, Edge is liable for violations of the Lanham Act and Chapter 93A, and the Court should enter judgment in favor of Azurity.

II. Azurity is Entitled to Damages for Edge’s Violations of the Lanham Act and Chapter 93A.

Section 1117(a) of the Lanham Act provides that a successful plaintiff is entitled, “subject to the principles of equity, to recover (1) defendant’s profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action.” 15 U.S.C. § 1117(a). In the First Circuit, a plaintiff seeking disgorgement must ordinarily prove both “actual harm” and “direct competition.” *Aktiebolaget Electrolux v. Armatron Int’l Inc.*, 999 F.2d 1, 5 (1st Cir. 1993). However, “the general rule of direct competition is loosened if the defendant acted fraudulently or palmed off inferior goods, such that actual harm is presumed; and ... where defendant’s inequitable conduct warrants bypassing the usual rule of actual harm, damages may be assessed on an unjust enrichment or deterrence theory.” *Id.* Thus, in the absence of actual harm and direct competition, “damages may be awarded upon one of three conditions: the defendant acted fraudulently; to avoid unjust enrichment of the defendant; or to deter further willful misconduct.” *Vermont Pure Holdings, Ltd. v. Nestle Waters N. Am., Inc.*, Civ. A. No. 03-11465, 2006 WL 839486, at *11 (D. Mass. Mar. 28, 2006) (citing *Aktiebolaget Electrolux*, 999 F.2d at 5); *see also Nat’l Fire Prot. Ass’n v. Int’l Code Council, Inc.*, Civ. A. No. 03-10848, 2006 WL 839501, at *28 (D. Mass. Mar. 29, 2006) (noting

that actual harm may be presumed in cases of willful and fraudulent violations of the Lanham Act).³

The First Circuit in *Tamko Roofing Products, Inc. v. Ideal Roofing Co.*, 282 F.3d 23, 35 (1st Cir. 2002) identified three justifications for awarding defendant's profits as a measure of plaintiff's damages: "(1) as a rough measure of the harm to plaintiff; (2) to avoid unjust enrichment of the defendant; or (3) if necessary to protect the plaintiff by deterring a willful infringer from further infringement." *Id.* at 36. The *Tamko* court further stated that "[i]n cases of at least some direct competition and willfulness, some role may exist for deterrence in an award of an accounting of profits." *Id.* at 38.

Moreover, this Court held in *HipSaver Co. v. J.T. Posey Co.*, 497 F. Supp. 2d 96, 109 (D. Mass. 2007) that "the weight of the caselaw in this circuit supports a rebuttable presumption of causation and injury for willful literally false advertising in a two firm market where a defendant makes comparative statements targeting a direct competitor's products."

Here, Edge manufactured a liquid formulation of vancomycin hydrochloride for oral solution that was in direct competition with Azurity's FIRVANQ®. Moreover, between April 2018 and September 2019 (the "Relevant Period"), Edge was the only 503(b) compounding pharmacy that Azurity is aware of that compounded liquid vancomycin hydrochloride, and as such,

³ See *HipSaver Co. v. J.T. Posey Co.*, 497 F. Supp. 2d 96, 107–08 (D. Mass. 2007) (noting that other circuits "have permitted a plaintiff to recover in Lanham Act cases, even in the absence of direct evidence of actual harm, under a similar 'totality of the circumstances' approach"). Under this approach, "an inability to show actual damages does not alone preclude a [monetary] recovery under section 1117." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1146 (9th Cir. 1997). Rather, the court may award relief based on "the totality of the circumstances." *Id.*; see also *Badger Meter, Inc. v. Grinnell Corp.*, 13 F.3d 1145, 1157 (7th Cir. 1994) (stating that, even if a plaintiff is unable to demonstrate damages resulting from the defendant's Lanham Act violation, § 1117 allows the district court to award the plaintiff any just monetary award so long as it constitutes "compensation" for the plaintiff's losses or the defendant's unjust enrichment and is not simply a "penalty" for the defendant's conduct).

Azurity and Edge were direct competitors in the market for liquid formulation of vancomycin hydrochloride for oral solution. Ex. F, Decl. of S. Monahan ¶¶ 7-8. Thus, Edge made literally false advertisements in a market where Azurity was its direct competitor, entitling Azurity to a rebuttable presumption of causation and injury for willfully false statements, sufficient to support a claim for disgorgement of Edge's profits.

However, Azurity does not have any information whatsoever about Edge's sales. Edge has ceased to participate in this lawsuit, and as a result, Azurity is unable to obtain discovery regarding Edge's profits during the Relevant Period. Nonetheless, Azurity has substantial experience with the market for FIRVANQ® from 2018 to the present, including analysis of its own sales data as well as access to industry-accepted statistics and data on the demand for vancomycin hydrochloride. *Id.* ¶ 9. As such, Azurity's calculates its damages based on actual sales of FIRVANQ®, and the expected increase in sales during the time that Edge and Azurity operated as direct competitors. *Id.* ¶ 8. During the Relevant Period, Azurity's total sales were \$[REDACTED]. *Id.* ¶ 11. Based on Azurity's analysis of FIRVANQ® sales data and its familiarity with the vancomycin hydrochloride market, Azurity's conservative judgment is that, without Edge's competing liquid formulation of vancomycin in the market, FIRVANQ® sales during the Relevant Period would have been at least [REDACTED] percent ([REDACTED]%) higher than they were. *Id.* ¶ 10. Therefore, Edge's false statements damaged Azurity in the amount of \$[REDACTED]. *Id.* ¶ 12.

Azurity has thus provided an estimate of its lost profits during the period when Edge made literally false statements. This estimate is based on Azurity's experience in the market and the best data and information available to Azurity, particularly given that no discovery was taken in this matter, and given that Edge is no longer operating. Moreover, Edge falsely advertised non-compliant, compounded vancomycin that created a risk to the health and safety of patients.

Although Edge is no longer in business, entering judgment as requested by Azurity will deter other compounding pharmacies from engaging in similar bad acts. Accordingly, equity warrants entering judgment in favor of Azurity in the amount of \$ [REDACTED], and this motion should be granted.

CONCLUSION

Edge's website falsely represented that its business practices were compliant with section 503B and FDA regulations generally to attract customers. These misrepresentations constitute a violation of section 43(a) of the Lanham Act and Massachusetts' unfair and deceptive trade practices law. For these reasons, Azurity is entitled to judgment in its favor and damages totaling \$ [REDACTED].

Date: February 2, 2023

Respectfully submitted,

/s/ James H. Hulme

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CERTIFICATE OF SERVICE

I hereby certify that on February 2, 2023 the foregoing document was served via certified mail on the following party:

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